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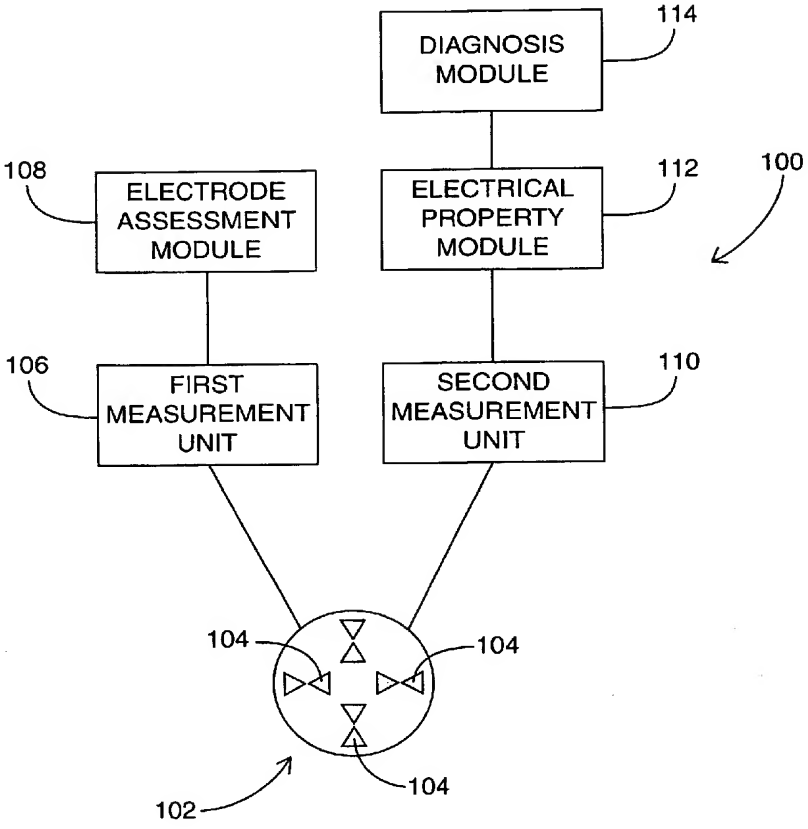

(57) Abstract: A system and method for diagnosing the possibility of disease in a body part is described. The system includes an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part. A first measurement unit makes an electrode assessment measurement with the electrode array. An electrode assessment module determines whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement. If there is suitable coupling, a second measurement unit makes a diagnosis measurement with the electrode array. An electrical property module obtains an electrical property of the body part, such as impedance, based on the diagnosis measurement. A diagnosis module diagnoses the possibility of disease based on the measured electrical property.

WO 2004/047636 A1

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APPARATUS FOR DETERMINING ADEQUACY OF ELECTRODE-TO-SKIN CONTACT AND ELECTRODE QUALITY FOR BIOELECTRICAL MEASUREMENTS

Cross-Reference To Related Application

This application claims priority from provisional application serial no. 60/429,316 filed November 27, 2002.

Field of the invention

This invention relates to medical diagnosis of disease and specifically relates to diagnosis of disease using electrical impedances of body parts.

Background of the invention

The onset of disease is often accompanied by physical changes in a body part. Some physical changes, while not discernible by a patient, can be detected with appropriate diagnostic equipment, often at a relatively early stage of the disease. For example, the electrical impedance of a human breast can have diagnostic value.

Electrical impedances of various body tissues are well known through studies on intact humans or from excised tissue made available following therapeutic surgical procedures. In addition, it is well documented that a decrease in electrical impedance occurs in tissue as it undergoes cancerous

changes. This finding is consistent over many animal species and tissue types, including, for example human breast cancers.

There have been a number of reports of attempts to detect breast tumors using electrical impedance imaging, such as, for example, U.S. Pat. No. 4,486,835. However, image fidelity and resolution can suffer when simplifying assumptions are made in mathematical models used to construct an image from impedance data.

Despite such difficulties, a method that permits comparisons of electrical properties for diagnostic purposes has been developed that involves homologous body parts, i.e., body parts that are substantially similar, such as a left breast and a right breast. In this method, the impedance of a body part of a patient is compared to the impedance of the homologous body part of the *same* patient. One technique for screening and diagnosing diseased states within the body using electrical impedance is disclosed in U.S. Pat. No. 6,122,544, which is incorporated herein by reference. In this patent, data are obtained from two anatomically homologous body regions, one of which may be affected by disease. Differences in the electrical properties of the two homologous body parts could signal disease.

Published international patent application, PCT/CA01/01788, which is incorporated herein by reference, discloses a breast electrode array for

diagnosing the presence of a disease state in a living organism, wherein the electrode array comprises a flexible body, a plurality of flexible arms extending from the body, and a plurality of electrodes provided by the plurality of flexible arms, wherein the electrodes are arranged on the arms to obtain impedance measurements between respective electrodes. In one embodiment, the plurality of flexible arms are spaced around the flexible body and are provided with electrode pairs, which can be used to make tetrapolar impedance measurements.

Tetrapolar impedance measurements are associated with injecting current between so called current injection electrodes and measuring a voltage drop between associated electrodes. In a preferred embodiment, the differences between corresponding homologous impedance measurements in the two body parts are compared in a variety of ways that allows the calculation of metrics that can serve either as an indicator of the presence of disease or to localize the disease to a specific breast quadrant or sector.

Despite the attractive features of this method of diagnosing disease in one of a homologous pair of body parts, there are some problems associated with this straightforward implementation. In particular, some impedances obtained from electrical measurements may be spurious because of systematic errors occurring therein. Spurious impedances can lead to a faulty

diagnosis. Therefore, any test that can be performed at the outset to test and correct for such error would increase diagnostic accuracy.

Summary of the invention

To determine the impedance of a body part, such as a breast, for diagnostic purposes, several electrical measurements are performed with an electrode array having a plurality of electrodes in contact with the skin covering the underlying breast tissue. If one or more electrodes have lost contact with the skin, or if the contact with the skin is poor, errors can arise in the electrical measurements that then yield erroneous impedances.

The present invention provides a method to determine both if there is electrode contact with the skin, and, if there is such contact, what the quality of that contact is. The method involves making bipolar measurements of the impedance.

In an AC circuit, the impedance, Z, is a complex number, whose real part is the resistance R and whose imaginary part is the capacitive reactance $X_C = (\omega C)^{-1}$, where ω is the frequency at which the voltage (and current) oscillates and C is the capacitance of the circuit. The magnitude of Z is given by

$$|Z| = |V| / |I|,$$

and the phase, ϕ, of Z is given by

$$|\phi| = |\arg(V) - \arg(I)|$$

$$= \left|\tan^{-1}[X_C(\omega)/R]\right|,$$

where I denotes the current and V denotes the voltage.

The phase associated with a body part of a patient at a particular frequency can be found by making bipolar measurements. By comparing the phase, at one or several frequencies, to expected values, a decision can be made as to whether the electrode is in suitable contact with the skin on the body part.

Whereas impedance is most accurately measured using the tetrapolar method, bipolar measurement is better for determining adequacy of electrode-to-skin contact (herein referred to as either "contact" or "electrode contact") because a poor contact result can be isolated to one or both electrodes. There are changes in both impedance magnitude and phase with deteriorating contact, but using phase instead of the magnitude is advantageous because a) impedance magnitude varies greatly from person to person, b) stray capacitance in the system can cause a smaller observed impedance value than would be expected from the high open-circuit value associated with a disconnected electrode, and c) sweat or some other substance could allow a low impedance to be registered even though the current traversing the skin is reduced because of poor electrode contact.

Measuring the phase at different frequencies allows this measure to be even more precise because it can identify if excessive oil or other materials obstruct the skin-electrode interface. In the case of a multi-frequency contact assessment, the expected value for human skin at each of these frequencies is considered. With multiple frequencies, the measured ratio between measured impedance values at different frequencies can be compared to the expected values oh human skin.

Described herein is a system and method for diagnosing the possibility of disease in a body part, such as a human breast. The system includes an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part, and a first measurement unit for making an electrode assessment measurement for the electrode array. The system also includes an electrode assessment module for determining whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement. The system further includes a second measurement unit for making a diagnosis measurement with the electrode array, and an electrical property module for obtaining an electrical property, such as electrical impedance, of the body part based on the diagnosis measurement. A diagnosis module utilizes the electrical property to diagnose the possibility of disease.

In one embodiment, the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode

pair that are applied to the body part. One current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair are used by the first measurement unit to make a bipolar measurement.

The electrode assessment module can include a phase module for obtaining a phase, ϕ, from the bipolar measurement, whose absolute value is given by

$$|\phi| = \left|\tan^{-1}[X_C(\omega)/R]\right|$$

where $X_C(\omega)$ is a capacitive reactance at an alternating frequency, ω, of a current injected during the bipolar measurement, and R is a resistance associated with the body part. The electrode assessment module may further include a contact module for determining that at least one of the current injection electrode and the voltage measurement electrode is not in electrical contact with the body part if the phase is outside a threshold range.

The electrode assessment module can also include a magnitude module for computing a magnitude, Z, from the bipolar measurement, the magnitude given by

$$Z = \left|\frac{V}{I}\right|,$$

where I is the current and V is a resultant voltage measured during the bipolar measurement, and a quality module for determining quality of electrical contact of the current injection electrode and the voltage measurement electrode with the body part based on the magnitude.

In one embodiment, the electrode assessment module may include a) a phase module for obtaining a phase that is a function of a capacitive reactance, at a particular frequency, and a resistance, associated with the body part, and for obtaining other phases at other frequencies, and b) a contact module for determining that at least one of the current injection electrode and the voltage measurement electrode is not in electrical contact with the body part based on the phase at the particular frequency and the other phases at the other frequencies.

The plurality of electrodes mentioned above can include n_{CI} current injection electrode pairs and n_{CI} associated voltage measurement electrode pairs that are applied to the body part. The second measurement unit injects a first current between a first pair of the n_{CI} current injection electrode pairs, measures the resultant voltage difference V_1^M between the voltage measurement electrode pair associated with the first current injection electrode pair, and repeats the preceding two steps of current injection and voltage difference measurement with the other electrode pairs until all n_{CI} voltage differences, $\{V_1^M, V_2^M, \ldots, V_{n_{CI}}^M\}$ are obtained.

In one embodiment, the electrical property module is an impedance module that uses the n_{CI} voltage differences to obtain associated measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$, where Z_j^M is the measured impedance between the voltage electrodes associated with the *j*th current injection electrode pair. The system can then further include a diagnosis module for utilizing the measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$ to diagnose the possibility of disease.

In one embodiment, the system may also include a graphical user interface to indicate a status of the coupling between the plurality of electrodes and the body part.

The present invention describes a system and/or method for measuring an electrical property, such as impedance, in a living tissue that includes an electrode array, first and second measurement units, an electrode assessment module, and an electrical property module, which are described in more detail below.

Brief description of the drawings

Figure 1 shows a block diagram of the system for diagnosing the possibility of disease, according to the teachings of the present invention;

Figure 2A shows the electrode array of Figure 1.

Figure 2B shows a side view of a schematic of a particular current injection electrode pair and an associated voltage measurement electrode pair on the electrode array of Figure 1.

Figure 3 shows the electrode assessment module of Figure 1.

Figure 4 shows a graphical user interface (GUI) that illustrates the status of the skin-electrode contact, according to the teachings of the present invention.

Figure 5 shows a block diagram of a system for measuring a voltage in a body part, according to the teachings of the present invention.

Figures 6A-D shows modes of the controller switching unit of Figure 5.

Figure 7 shows a hybrid mode of the controller switching unit of Figure 5.

Figure 8 shows electrical connections in a particular tetrapolar impedance measurement that employs the system of Figure 5.

Figures 9A and 9B show the multiplexer of Figure 5.

Figure 10 shows a diagnostic system that includes an internal load in addition to the components of Figure 5.

Figure 11 shows one embodiment of the controller switching unit, according to the principles of the present invention.

Detailed description of the invention

Figure 1 shows a system 100 for diagnosing the possibility of disease in a body part. The system 100 includes an electrode array 102 containing a plurality of electrodes 104 capable of being electrically coupled to the body part. The system 100 also includes a first measurement unit 106, an electrode assessment module 108, a second measurement unit 110, an electrical property module 112 and a diagnosis module 114.

The plurality of electrodes 104 are applied to the body part to obtain an electrical property of the body part, such as impedance, to diagnose disease.

For this purpose, the plurality of electrodes 104 have to be electrically connected to the body part. For example, adhesive means (not shown) can be used to connect the electrodes 104 to the skin on the body part of a subject. The electrode conductive material, generally a hydrogel, can also have adhesive properties. The combined adhesive means can fail, resulting in an electrode that is not in proper electrical contact with the body part. To assess the adequacy of electrode coupling to the body part, the first measurement unit 106 utilizes the electrode array 102 to make an electrode assessment measurement. The electrode assessment module 108 determines whether the plurality of electrodes 104 are adequately coupled to the body part based on the electrode assessment measurement, as described in more detail below.

If the electrode assessment module 108 determines that the plurality of electrodes are suitably coupled to the body part, the second measurement unit 110 can then utilize the electrode array 102 to make a diagnosis measurement. The electrical property module 112 obtains an electrical property of the body part, such as an impedance of the body part, based on the diagnosis measurement. The diagnosis module 114 diagnoses the possibility of disease based on the electrical property. For example, cancer

may change the impedance of the body part, a fact that can be exploited by the diagnosis module 114 to diagnose the possible presence of cancer.

Figure 2A shows the electrode array 102 of Figure 1. The electrode array 102 includes the plurality of electrodes 104 that are applied to the body part. The plurality of electrodes 104 include current injection electrodes 120 and voltage measurement electrodes 122 (two of these electrodes are labeled for simplicity). In general, there are n_e current injection electrodes and n_e voltage measurement electrodes in the electrode array 102 (in Figure 2A, an example is shown with n_e=12). Consequently, there are $n_{CI} = n_e \cdot (n_e-1)/2$ combinations of current injections, and an equal number of voltage measurements.

The electrode array 102 contains several arms 123 (one arm is labeled for simplicity). Each arm includes a current injection electrode and a voltage measurement electrode. For example, the arm 125 includes a particular current injection electrode 124 and voltage measurement electrode 126. It is to be noted, however, that these electrodes can be physically identical and that the terms "current injection" and "voltage measurement" refer to their use during tetrapolar measurement, as used in this invention for the diagnosis stage. In addition, an inner pair of electrodes is provided on some of the array arms 123. One particular inner set of electrodes 128i and 130i is located on arm 127. By positioning the inner set of electrodes partway on the array arms, these electrodes are placed closer to the nipple area of the

breast, thus allowing better detection of cancers in the periareolar area of the breast.

For *tetrapolar* measurements, which are discussed below, current injection electrode pairs are used to send current through the body part, and voltage measurement electrode pairs are used to measure the resultant voltage. For example, Figure 2B shows a side view of the particular current injection electrode 124 and the voltage measurement electrode 126 on the arm 125. Also shown in Figure 2B is another arm 127 of the electrode array 102 having another current injection electrode 128 and voltage measurement electrode 130.

For *bipolar* measurements, however, a single electrode is used for both current injection and voltage measurement. For example, referring again to arm 25 of Figure 2B, current is injected between electrodes 124 and 126, and voltage is measured between electrodes 124 and 126. More specifically, current is injected through electrode 124 into the body part, then is received from the body part through electrode 126. The resultant voltage difference between electrodes 124 and 126 is measured by a voltmeter 131. The first measurement unit 106 is used to make the bipolar impedance measurement between electrodes 124 and 126, yielding a reactance X_C and a resistance R The result of this bipolar measurement is used to assess whether the electrodes on the arm 125 are suitably coupled to the body part before a tetrapolar measurement is performed to diagnose disease.

In Figure 2B, adjacent electrodes 124 and 126 are used to perform the bipolar measurements. This choice is dictated by the fact that a measurement is more likely to yield predominantly electrode-to-skin contact impedance if the distance between the two electrodes used is very small.

Figure 3 shows the electrode assessment module 108 of Figure 1. The electrode assessment module 108 includes a phase module 132, a magnitude module 134, a contact module 136 and a quality module 138.

The phase module 132 obtains a phase ϕ from the bipolar measurement according to

$$|\phi| = \left|\tan^{-1}[X_C(\omega)/R]\right|$$

The contact module 136 uses the phase calculated by the phase module 132 to determine whether at least one of the electrodes 124 and 126 does not make adequate electrical contact with the body part. In particular, if the phase lies outside a threshold range, then the electrodes 124 and/or 126 fails to make adequate electrical contact with the skin. A useful index for this determination is the ratio X_C/R, with X_C/R < 0.80 at 50 kHz indicating failed contact. For multiple frequencies, the relationship between the phases at each frequency is used to make the contact determination. Particularly, as frequency increases, the phase of the impedance reduces. If the measured

phase at one frequency is larger than a measured phase at a lower frequency, something other than skin is making contact.

The magnitude module 134 obtains an impedance magnitude $|Z|$ from the bipolar measurement, the magnitude given by

$$|Z| = |V / I|$$
$$= \sqrt{R^2 + X_C^2}$$

The quality module 138 uses the magnitude $|Z|$ calculated by the magnitude module 134 to determine the quality of the conductive hydrogel in electrode 124 and/or 126. For example, as the electrodes are exposed to heat or air, the gel dries, decreasing its conductivity. This causes a significant increase in the magnitude of the bipolar impedance measured between electrodes 124 and 126. For example, at 50 kHz measurement, a magnitude greater than 1800 ohms has been found to indicate significant hydrogel deterioration.

Thus, the first measurement unit 106 makes bipolar measurements that allow the electrode assessment module 108 to determine a) whether the electrodes 124 and 126 are in adequate contact with the skin, as ascertained from the phase information and b) whether the conductive quality of the hydrogel component of electrodes 124 and 126 has been maintained or has

deteriorated, as ascertained from the impedance magnitude. It should be understood that the electrode-to-skin contact of other electrodes can also be assessed. For this purpose, another bipolar measurement can be performed using another two electrodes on another arm of the electrode array to provide information about the suitability of the contact, and so on.

Figure 4 shows a graphical user interface (GUI) that illustrates the status of the electrode-to-skin contact. A display 150 shows two representations 152 and 154 of electrode arrays 102, the representation 152 of the right breast array and the representation 154 of the left breast array. Each electrode array representation has twelve arms 156. In another embodiment, each electrode array representation has sixteen arms. The colour of the circles 158 indicates which electrodes have been ascertained to be in contact with the skin. In one embodiment, a red circle indicates an inadequate contact, and a blue circle indicates an adequate one. Other indicators are possible, such as flashing circles representing inadequate contacts. For the purposes of explanation, white circles represent electrodes making adequate contact, and black circles represent those that are not. This determination is made by the contact module 136.

The quality module 138, furnishes its information at the bottom of the display. Here, a bar 160 is shown with various levels of electrode quality with, in this example, three usable levels—Excellent, Good, and Pass—and one

unacceptable level—Replace. If the quality is excellent, for example, then the word "Excellent" is highlighted on the bar 160.

Both electrode contact and quality information are made available to the user administering the diagnostic examination in real time. Thus, the user can take immediate steps to rectify a poor electrode-to-skin contact, or replace a deteriorated electrode, before proceeding with the diagnostic testing. The ability to display real time information is a direct result of using bipolar measurements for making the status determination. With bipolar measurements, one measurement relates to one electrode pair, and only the number of measurements as there air pairs is required to refresh the display. If tetrapolar measurements were used to make the contact determination, each measurement would include four electrodes and many sets of measurements per pair would be required to make the contact determination. Performing all of these measurements would take much longer.

The display 150 shown can be a computer or television monitor. In other embodiments, LED lights can signal electrode status.

If the results of the electrode assessment module 108 indicate that the status of the plurality of electrodes 104 is suitable, then the system 100 can proceed to the diagnosis stage. The second measurement unit 110 injects a first current between a first pair of the n_{CI} current injection electrode pairs, and

then measures the resultant voltage difference V_1^M between a voltage measurement electrode pair. In a preferred embodiment, if current travels from a current injection electrode of a first arm to a current injection electrode of a second arm, then the voltage difference is measured between the voltage measurement electrodes of the same two arms. In Figure 2B, for example, current can flow between electrodes 124 and 128. The associated resultant voltage is measured between electrodes 126 and 130. Thus, n_{CI} current injections are possible with an equal number of associated voltage measurements. By repeating the above described current injection and voltage measurement n_{CI} –1 more times each, a total of n_{CI} voltage differences, $\{V_1^M, V_2^M, \ldots, V_{n_{CI}}^M\}$ are obtained.

The impedance module 112 uses the n_{CI} voltage differences to obtain associated measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$, where Z_j^M is the measured impedance between the voltage electrodes associated with the jth current injection electrode pair.

The diagnosis module 114 utilizes the measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$ to diagnose the possibility of disease. For example, U.S. Pat. No. 6,122,544 describes a method that compares impedances between homologous body parts. In this method, the impedance of a body part of a patient is compared to the impedance of the homologous body part of the

same patient. A difference between these two impedances could signal disease.

As described above, the system 100 employs both tetrapolar and bipolar measurements to assess the quality of electrode contact. A diagnostic system 1000 capable of both these types of measurements will now be described.

Figure 5 shows a system 1000 for measuring a voltage in a body part 110, such as a human breast. The system 1000 includes N body leads 120. In what follows, the N body leads 120 are ordered from 1 to N for reference. The system 1000 also includes a multiplexing unit 140 having a multiplexer 160, a first MX lead 180, a second MX lead 200, a third MX lead 220 and a fourth MX lead 240.

The system 1000 further includes a controller switching unit 260 having a first switch 280 connected to the multiplexer 160 by the first MX lead 180 and the second MX lead 200, a second switch 300 connected to the multiplexer 160 by the third MX lead 220 and the fourth MX lead 240, a current input lead 320 connected to the first switch 280, a current output lead 340 connected to the second switch 300, a first voltage lead 360 connected to the first switch 280, and a second voltage lead 380 connected to the second switch 300. The controller switching unit 260 also includes a controller 390.

The system 1000 further includes an impedance module 400 and a diagnosis module 420.

Also shown in Figure 5 is an optional second set of leads 440 that can be used when making measurements on a second homologous body part 460. The description below is directed mainly to an impedance measurement on the one body part 110 with the set of N leads 120, but it should be understood that the discussion could be analogously expanded to include an impedance measurement on the second homologous body part 460 with the second set of leads 440. Thus, the principles of the present invention can be applied to diagnosis of disease by making electrical measurements on a single body part, or by making measurements on a homologous pair of body parts. When making measurements on only a single body part, the results can be compared to standard results obtained from population studies, for example, to diagnose disease. When using a homologous pair of body parts, the results of one body part can be compared to the results of the homologous body part of the same patient, as described in U.S. Patent No. 6,122,544.

The N body leads 120 electrically connect the multiplexing unit 140 to the body part 110. Each of the N body leads 120 includes a wire capable of carrying a current and an electrode to attach to the body part 110. A current

conducting gel can act as an interface between the electrode and the skin covering the body part 110.

The multiplexing unit 140 and the controller switching unit 260 allow a current to flow through the body part 110 between any two body leads, n_1 and n_2, of the N body leads 120, and a resultant voltage to be measured between any two body leads, n_3 and n_4 of the N body leads 120, where $n_1 \neq n_2$ and $n_3 \neq n_4$, but where n_1, n_2, n_3 and n_4 need not otherwise be distinct. Thus, n_1, n_2, n_3, and n_4 are numbers belonging to the set $\{1,2,...,N\}$ that identify body leads. For example, if $n_1 = 7$, then n_1 denotes the seventh body lead from among the N body leads 120 used to inject current into the body part 110.

The impedance module 400 generates current that is injected into the current input lead 320 and then delivered to the body part. The current output lead 340 receives the current from the body part. When the current is traveling through the body part, the first voltage lead 360 and the second voltage lead 380 are used to measure the resultant voltage between these leads 360 and 380. The impedance module 400 uses this voltage, together with the known current injected into the current input lead 320, to calculate a corresponding impedance, which may then be used by the diagnosis module 420 to diagnose disease.

In one embodiment, N is even and the multiplexer 160 can electrically connect the first MX lead 180 and the fourth MX lead 240 to a first set of N/2 of the N leads, and the second MX lead 200 and the third MX lead 220 to a second set of the other N/2 leads. In a conventional system, the first set of N/2 leads are exclusively used to inject current into and receive current from the body part. The second set of N/2 leads are then exclusively used to measure resultant voltages in tetrapolar measurements. This configuration limits the number of impedances that can be measured.

In the system 1000, however, the second set of N/2 leads can also be used to inject and receive current, and the first set can be used to measure resultant voltages. Thus, the system 1000 can furnish a greater number of impedances. Moreover, as detailed below, the system can make both tetrapolar and bipolar measurements. The added benefits arise from the functionality of the controller switching unit 260. By using the controller switching unit 260, the system 1000 can force current to flow through the body part 110 between any two body leads, n_1 and n_2, of the N body leads 120, and a resultant voltage to be measured between any two body leads, n_3 and n_4 of the N body leads 120, where $n_1 \neq n_2$ and $n_3 \neq n_4$.

Figures 6A-D show several states of the switches 280 and 300 resulting in different modes of the controller switching unit 260 of the system of Figure 5. These states of the switches 280 and 300 are controlled by the

controller 390. In Figure 6A, current is injected into the first MX lead 180 and received by the fourth MX lead 240. While this current travels through the body part 110, a resultant voltage is measured between the second MX lead 200 and the third MX lead 220. This measurement is tetrapolar because current is forced to flow between two leads and the resultant voltage is measured between two other leads.

In Figure 6B, current is injected into the second MX lead 200 and received by the third MX lead 220. The resultant voltage is measured between the first MX lead 180 and the fourth MX lead 240. This measurement is also tetrapolar.

In Figures 6A and 6B, the first switch 280 and the second switch 300 are both in tetrapolar states since, for each of the switches 280 and 300, two distinct MX leads are involved in the impedance measurement. When both switch states are tetrapolar, the controller switching unit 260 is said to be in a tetrapolar mode. Thus, Figures 6A and 6B correspond to tetrapolar modes.

In a tetrapolar mode, the current input lead 320 is electrically connected to exactly one of the first MX lead 180 and the second MX lead 200 and the first voltage lead 360 is electrically connected to the other one of the first MX lead 180 and the second MX lead 200; likewise, the current output lead 340 is electrically connected to exactly one of the third MX lead

220 and the fourth MX lead 240 and the second voltage lead 380 is connected to the other one of the third MX lead 220 and the fourth MX lead 240.

The two tetrapolar modes shown in Figures 6A and 6B do not exhaust all the tetrapolar modes. For example, when the first switch 280 state is the same as the state shown in Figure 6A and the second switch 300 state is the same as the state shown in Figure 6B, the controller switching unit 260 is also in a tetrapolar mode. Generally, the controller switching unit 260 is in a tetrapolar mode when n_1, n_2, n_3 and n_4 are distinct, where n_1 and n_2 are leads from among the N leads 120 used to inject current into and receive current from the body part 110, and n_3 and n_4 are leads used to measure the resultant voltage.

In Figure 6C, current is injected into the first MX lead 180 and received by the fourth MX lead 240. While this current travels through the body part 110, a resultant voltage is measured between the first MX lead 180 and the fourth MX lead 240. The second and third MX leads 200 and 220 are electrically unconnected to any of the N body leads 120 during this measurement. This measurement is bipolar because the pair of electrodes used for measuring a voltage is also used for current flow.

In Figure 6D, current is injected into the second MX lead 200 and received by the third MX lead 220. The resultant voltage is measured between the same two leads 200 and 220. The first and fourth MX leads 180 and 240 are electrically unconnected during this measurement. This measurement is also bipolar.

In Figures 6C and 6D, the first switch 280 and the second switch 300 are both in bipolar states since, for each of the switches 280 and 300, only one MX lead is involved in the impedance measurement. When both switch states are bipolar, the controller switching unit 260 is said to be in a bipolar mode. Thus, Figures 6C and 6D correspond to bipolar modes.

In a bipolar mode, the current input lead 320 and the first voltage lead 360 are electrically connected to each other and to exactly one of the first MX lead 180 and the second MX lead 200, and the current output lead 340 and the second voltage lead 380 are electrically connected to each other and to exactly one of the third MX lead 220 and the fourth MX lead 240.

The two modes shown in Figures 6C and 6D do not exhaust all bipolar modes. For example, when the first switch 280 state is the same as the state shown in Figure 6C and the second switch 300 state is the same as the state shown in Figure 6D, the controller switching unit 260 is also in a bipolar mode. More generally, the controller switching unit 260 is in a bipolar mode when

$n_1 = n_3$ or n_4, and $n_2 = n_3$ or n_4, where n_1 and n_2 are leads from among the N leads 120 used to inject and receive current, and n_3 and n_4 are leads used to measure the resultant voltage.

In addition to the tetrapolar and bipolar modes shown in Figures 6A-6D, there are also hybrid modes. Figure 7 shows a hybrid mode of the controller switching unit 260 of Figure 5. Here, the first switch 280 is in a tetrapolar state and the second switch 300 is in a bipolar state. In a hybrid mode, $n_1 \neq n_3$ and $n_2 = n_4$, or $n_1 \neq n_4$ and $n_2 = n_3$, where again n_1 and n_2 are used for current flow and n_3 and n_4 are used for voltage measurement.

In Figure 7, the lead n_1 is electrically connected to the first MX lead 180 or to the fourth MX lead 240 via the multiplexer 160. The lead n_2 is connected to whichever of first MX lead 180 and the fourth MX lead 240 is not connected to the lead n_1. The lead n_3 is connected to the second MX lead 200 or the fourth MX lead 240, and the lead n_4 is connected to whichever of the second MX lead 200 and the fourth MX lead 240 is not connected to the n_3 lead. The third MX lead 220 is electrically unconnected during this hybrid measurement.

Figure 8 shows electrical connections in a particular tetrapolar impedance measurement that employs the system 1000 of Figure 5. For

simplicity, the system 1000 has only N=10 leads, and the controller 390, the impedance module 400 and the diagnosis module 420 are not shown. In a different embodiment, N=32. Also not shown in the Figure 8 is the second set of leads 440. The ten electrodes of the ten leads are shown: the first set of N/2 = five electrodes 1-5 lie on the outside perimeter and the other set of five electrodes 6-10 lie on the inner perimeter.

All the electrodes 1-5 of the first set can be electrically connected to the first and fourth MX leads 180 and 240, and all the electrodes 6-10 of the second set can be connected to the second and third MX leads 200 and 220 via the multiplexer 160. In the example of Figure 8, the connections shown are for one tetrapolar measurement in which $n_1 = 6$, $n_2 = 9$, $n_3 = 2$ and $n_4 = 5$, where electrode 60 is used to inject current into the body part 110 and electrode 90 is used to receive the current. The electrodes 2 and 5 are used to measure the resultant voltage. Although all electrodes of the ten leads are shown in Figure 8, only the four wires of the electrically active leads appear.

In particular, current is generated by the impedance module 400 and sent to the current input lead 320. From there, the current travels to the first MX lead 180 via the first switch 280 and from there to the electrode 6 via the multiplexer 160. The current next travels through the body part 110 to the electrode 9 and then through the multiplexer 160 to the fourth MX lead 240. The current then flows to the current output lead 340 via the second switch

300 and then back to the impedance module 400. The resultant voltage is measured between the first and second voltage leads 360 and 380, which corresponds to the voltage between the electrodes 2 and 5. The first voltage lead 360 is connected to the electrode 2 via the first switch 280 and the multiplexer 160, and the second voltage lead 380 is electrically connected to the electrode 5 via the second switch 300 and the multiplexer 160. The controller 390 controls the states of the switches 280 and 300 and the multiplexing states in the multiplexer 160 that determine through which leads current flows and which leads are used to measure voltage.

Figure 9A shows the multiplexer 160 of Figure 5 in an embodiment in which a body part is being compared to a homologous body part. The multiplexer 160 includes a first body part multiplexer 520 that includes a first body part A multiplexer unit 540 and a first body part B multiplexer unit 560. The multiplexer 160 also includes a second body part multiplexer 580 that includes a second body part A multiplexer unit 600 and a second body part B multiplexer unit 620. The first body part A multiplexer unit 540 is connected to the first MX lead 180 and the fourth MX lead 240. The first body part B multiplexer unit 560 is connected to the second MX lead 200 and the third MX lead 220. Although not shown in the interest of clarity, the second body part A multiplexer unit 600 is also connected to the first MX lead 180 and the fourth MX lead 240, and the second body part B multiplexer unit 620 is also connected to the second MX lead 200 and the third MX lead 220.

The first body part multiplexer 520 is used for multiplexing electrical signals to the first body part of the homologous pair. In particular, the first body part A multiplexer unit 540 and B multiplexer unit 560 are both capable of multiplexing current and voltage signals to and from the N leads 120. Likewise, the second body part multiplexer 580 is used for multiplexing electrical signals to the homologous body part. In particular, the second body part A multiplexer unit 600 and B multiplexer unit 620 are both capable of multiplexing current and voltage signals to and from the N leads 120, as described below.

Figure 9B shows the first body part A multiplexer unit 540 of Figure 9A. The multiplexer unit 540 includes four one-to-N/4 multiplexers 640, 660, 680 and 700. These, for example, can be model number MAX4051ACPE manufactured by MAXIM™. The N/4 multiplexer current leads 720 connect the multiplexer 640 to the multiplexer 680, and N/4 multiplexer current leads 740 connect the multiplexers 660 and 700. In turn, the leads 720 and 740 are connected to the first N/2 of the N leads 120. The multiplexers 640, 660, 680 and 700 each have a configurable one bit "inhibit state" and $\log_2(N/4)$ bit "control state." The inhibit state can be either off (0) or on (1) and determines whether current can flow through the respective multiplexer 640, 660, 680 or 700. The control state determines through which one of the leads 720, 740 current flows. If N = 32, then four bits are required for each active multiplexer

(by "active" is meant that the inhibit state is off) and to specify a state, one for the inhibit state and three for the control state. For example, if the inhibit state of the multiplexer 640 is 1 (on) and the state of the multiplexer 660 is (0,0,0,1), where the first bit is for the inhibit state, and the last three bits identify which lead of multiplexer 660 is being activated, then current destined for the breast is directed to the tenth lead, provided the states of the switches 280 and 300 connect the current input lead 320 to the first MX lead 180, as previously described. If the states of the switches 280 and 300 do not connect the current input lead 320 to the first MX lead 180, but do connect the first voltage lead 360 to the first MX lead 180, then this lead 180, when the multiplexer 660 is in the state (0,0,0,1), measures the resultant voltage with the tenth lead.

A similar binary code for the multiplexers 680 and 700 dictates through which one of the first 16 electrodes of the 32 leads 120 current is received from the breast, provided the states of the switches 280 and 300 connect the current output lead 340 to the fourth MX lead 240. If the fourth MX lead 240 is not connected to the current output lead 340, but is connected to the second voltage lead 220, then the fourth MX lead 240 is used for measuring the resultant voltage, provided the inhibit state of the multiplexer 680 or the multiplexer 700 is off.

The B multiplexer unit 560 is similar to the A multiplexer unit 540 in that it has four one-to-N/4 multiplexers analogous to 640, 660, 680 and 700. However, the one-to-N/4 multiplexers are capable of connecting with the second and third MX leads 200 and 220, instead of the first and fourth MX leads 180 and 240. Here, the inhibit and control states determine which electrode from among the other N/2 electrodes is used to deliver current or measure voltage.

Thus, by setting inhibit and control states, in coordination with the states of the switches 280 and 300, it is possible to direct current between any pair of the N leads 120 and to make a measurement of the resultant voltage between any pair of the N leads 120.

The inhibit and control states are set by the controller 390 with a shift-register and/or a computer. A direct digital stream can be sent to the shift register for this purpose.

The function of the second body part multiplexer 580 is analogous to that of the first body part multiplexer 520 and therefore need not be described further.

Figure 10 shows a diagnostic system 820 that includes an internal load 840 in addition to the components described above in relation to Figure 5. The internal load 840 is electrically connected to the first MX lead 180, the second MX lead 200, the third MX lead 220 and the fourth MX lead 240. The internal load 840 is used for at least one of internal testing of the system 820 and varying the measurment range of the system 820.

Using the first switch 280 and the second switch 300, the internal load 840 can be connected to the impedance module 400 in a tetrapolar mode or in a bipolar mode. The internal load 840 has a known impedance and therefore can be used to test the diagnostic system 820.

Additionally, the internal load 840 can be used to change the measurement range of the system 820. By attaching this internal load 840 in parallel with any load, such as the body part 110, the system 820 is capable of measuring larger impedances than would otherwise be possible. If the resistance of the internal load 840 is R_{int} and is in parallel, the measured resistance R is given by

$$R = (1/R_{\text{load}} + 1/R_{\text{int}})^{-1}$$

where R_{load} is the resistance of the load. Consequently, the measured resistance is reduced from the value without the internal load, thereby increasing the measurement range of the system 840.

The switches 280 and 300 allow current to flow between various pairs of electrodes on a body part, and resultant voltage to be measured between various pairs of electrodes, as described above with reference to Figures 5-10. In Figure 11, another embodiment of the controller switching unit is shown that can be used to achieve the states of Figures 6A-D using a different electrical circuit topology. The controller switching unit 900 of Figure 11 includes a first switch 920 and a second switch 940. The current input lead 320, the current output lead 340, the first voltage lead 360 and the second voltage lead 380 split to connect to both the first and second switches 920 and 940.

The switches 920 and 940 can be turned on or off and can be used to make tetrapolar and bipolar measurements. With only one of the switches 920 and 940 on, a tetrapolar measurement can be made. With both switches 920 and 940 on, a bipolar measurement can be made. For example, when the first switch 920 is on, and the second switch is off, the resultant functionality corresponds to that of Figure 6A, albeit achieved with a different circuit topology. In this example, current flows from the impedance module 400 along the current input lead 320, through the first switch 920, and then to the first MX lead 180. From there, the current proceeds to the multiplexer 160. Current is received from the multiplexer 160 along the fourth MX lead, and delivered to the current output lead 340 via the first switch 920. The

resultant voltage is measured between the second and third MX leads 200 and 220 with the use of the first and second voltage leads 360 and 380.

In another example, when the first switch 920 is off, and the second switch 940 is on, the resultant functionality corresponds to that of Figure 6B. Here, current from the impedance module 400 travels along the current input lead 320, across the second switch 940, then jumps to the second MX lead 200. Current is received along the third MX lead 220, from where it jumps to the current output lead 340 via the second switch 940. The voltage is measured between the first and fourth MX leads 180 and 240 with the use of the first and second voltage leads 360 and 380.

In yet another example, the first and second switches 920 and 940 are both on, which corresponds to Figures 6C or 6D. Precisely to which of these two figures this example corresponds is determined by the inhibit states of the multiplexer 160. For example, if the inhibit states of both of the one-to-N/4 multiplexers 640 and 660 are on, then bipolar measurements are performed with the second set of N/2 electrodes.

The controller switching unit 900 also includes an internal load switch 1080 that is connected to the internal load 840. The controller switching unit 900 and the internal load 840 are used to test the system and to increase the measurement range, as described above.

It should be understood that various modifications could be made to the embodiments described and illustrated herein, without departing from the present invention, the scope of which is defined in the appended claims. The present invention involves the use of an electrode array for measuring impedances of a breast to determine the condition thereof. However, although emphasis has been placed on describing a system for diagnosing breast cancer, the principles of the present invention can also be advantageously applied to other diseases of other body parts.

Claims:

What is claimed is:

1. A method for diagnosing the possibility of disease in a body part, the method comprising

providing an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part;

making an electrode assessment measurement with the electrode array;

determining whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement;

making a diagnosis measurement with the electrode array;

obtaining an electrical property of the body part based on the diagnosis measurement; and

diagnosing the possibility of disease based on the electrical property of the body part.

2. The method of claim 1, wherein the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode pair, the method further comprising, before the step of making an electrode assessment measurement,

applying the current injection electrode pair to the body part; and

applying the associated voltage measurement electrode pair to the body part.

3. The method of claim 2, wherein the step of making an electrode assessment measurement includes utilizing one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair to make a bipolar measurement.

4. The method of claim 3, wherein the step of determining whether the plurality of electrodes are suitably coupled includes

computing a phase ϕ, whose absolute value is given by

$$|\phi| = \left|\tan^{-1}[X_C(\omega)/R]\right|$$

where $X_C(\omega)$ is a capacitive reactance at an alternating frequency, ω, of a current injected during the bipolar measurement, and R is a resistance associated with the body part; and

if the phase is outside a threshold range, determining that at least one of the current injection electrode and the voltage measurement electrode is not in electrical contact with the body part.

5. The method of claim 4, wherein the step of determining whether the plurality of electrodes are suitably coupled further includes

computing a magnitude Z given by

$$Z = \left| \frac{V}{I} \right|,$$

where I is the current and V is a resultant voltage measured during the bipolar measurement; and

determining quality of electrical contact of the current injection electrode and the voltage measurement electrode with the body part based on the magnitude.

6. The method of claim 3, wherein the step of determining includes using a phase, which is a function of the capacitive reactance and the resistance, at a particular frequency, and other phases at other frequencies to establish that at least one of the current injection electrode and the voltage measurement electrode is not in electrical contact with the body part.

7. The method of claim 1, wherein the plurality of electrodes includes n_{CI} current injection electrode pairs, and n_{CI} associated voltage measurement electrode pairs, where n_{CI} is an integer greater than zero.

8. The method of claim 7, wherein the step of making a diagnosis measurement includes

applying the n_{CI} current injection electrode pairs on the body part; and

applying the n_{CI} voltage measurement electrode pairs on the body part.

9. The method of claim 8, wherein the step of making a diagnosis measurement further includes

injecting a first current between a first pair of the n_{CI} current injection electrode pairs;

measuring the resultant voltage difference V_1^M between the voltage measurement electrode pair associated with the first current injection electrode pair; and

repeating the preceding two steps of injecting and measuring with the other electrode pairs until all n_{CI} voltage differences, $\{V_1^M, V_2^M, \ldots, V_{n_{CI}}^M\}$ are obtained.

10. The method of claim 9, wherein the electrical property is impedance.

11. The method of claim 10, wherein the step of obtaining includes using the n_{CI} voltage differences to obtain associated measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$, where Z_j^M is the measured impedance between the voltage electrodes associated with the *j*th current injection electrode pair.

12. The method of claim 1, further comprising indicating a status of the coupling between the plurality of electrodes and the body part with a graphical user interface.

13. A system for diagnosing the possibility of disease in a body part, the system comprising

an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part;

a first measurement unit for making an electrode assessment measurement with the electrode array;

an electrode assessment module for determining whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement;

a second measurement unit for making a diagnosis measurement with the electrode array; and

an electrical property module for obtaining an electrical property of the body part based on the diagnosis measurement, wherein the electrical property is used to diagnose the possibility of disease.

14. The system of claim 13, wherein the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode pair that are applied to the body part.

15. The system of claim 14, wherein one current injection electrode of the current injection electrode pair and one proximal voltage measurement electrode of the voltage measurement electrode pair are used by the first measurement unit to make a bipolar measurement.

16. The system of claim 15, wherein the electrode assessment module includes

a phase module for obtaining a phase, ϕ, from the bipolar measurement, whose absolute value is given by

$$|\phi| = \left|\tan^{-1}[X_C(\omega)/R]\right|$$

where $X_C(\omega)$ is a capacitive reactance at an alternating frequency, ω, of a current injected during the bipolar measurement, and R is a resistance associated with the body part; and

a contact module for determining that at least one of the current injection electrode and the voltage measurement electrode is not in electrical contact with the body part if the phase is outside a threshold range.

17. The system of claim 16, wherein the electrode assessment module includes

a magnitude module for computing a magnitude, Z, from the bipolar measurement, the magnitude given by

$$Z = \left|\frac{V}{I}\right|,$$

where *I* is the current and *V* is a resultant voltage measured during the bipolar measurement; and

a quality module for determining quality of electrical contact of the current injection electrode and the voltage measurement electrode with the body part based on the magnitude.

18. The system of claim 15, wherein the electrode assessment module includes

a phase module for obtaining a phase that is a function of a capacitive reactance, at a particular frequency, and a resistance, associated with the body part, and for obtaining other phases at other frequencies; and

a contact module for determining that at least one of the current injection electrode and the voltage measurement electrode is not in electrical contact with the body part based on the phase at the particular frequency and the other phases at the other frequencies.

19. The system of claim 13, wherein the plurality of electrodes includes n_{CI} current injection electrode pairs and n_{CI} associated voltage measurement electrode pairs that are applied to the body part.

20. The system of claim 19, wherein the second measurement unit injects a first current between a first pair of the n_{CI} current injection electrode pairs, measures the resultant voltage difference V_1^M between the voltage measurement electrode pair associated with the first current injection electrode pair, and repeats the preceding two steps of current injection and

voltage difference measurement with the other electrode pairs until all n_{CI} voltage differences, $\{V_1^M, V_2^M, \ldots, V_{n_{CI}}^M\}$ are obtained.

21. The system of claim 20, wherein the electrical property is impedance, and the electrical property module is an impedance module.

22. The system of claim 21, wherein the impedance module uses the n_{CI} voltage differences to obtain associated measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$, where Z_j^M is the measured impedance between the voltage electrodes associated with the jth current injection electrode pair.

23. The system of claim 22, further comprising a diagnosis module for utilizing the measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{n_{CI}}^M\}$ to diagnose the possibility of disease.

24. The system of claim 13, further comprising a graphical user interface to indicate a status of the coupling between the plurality of electrodes and the body part.

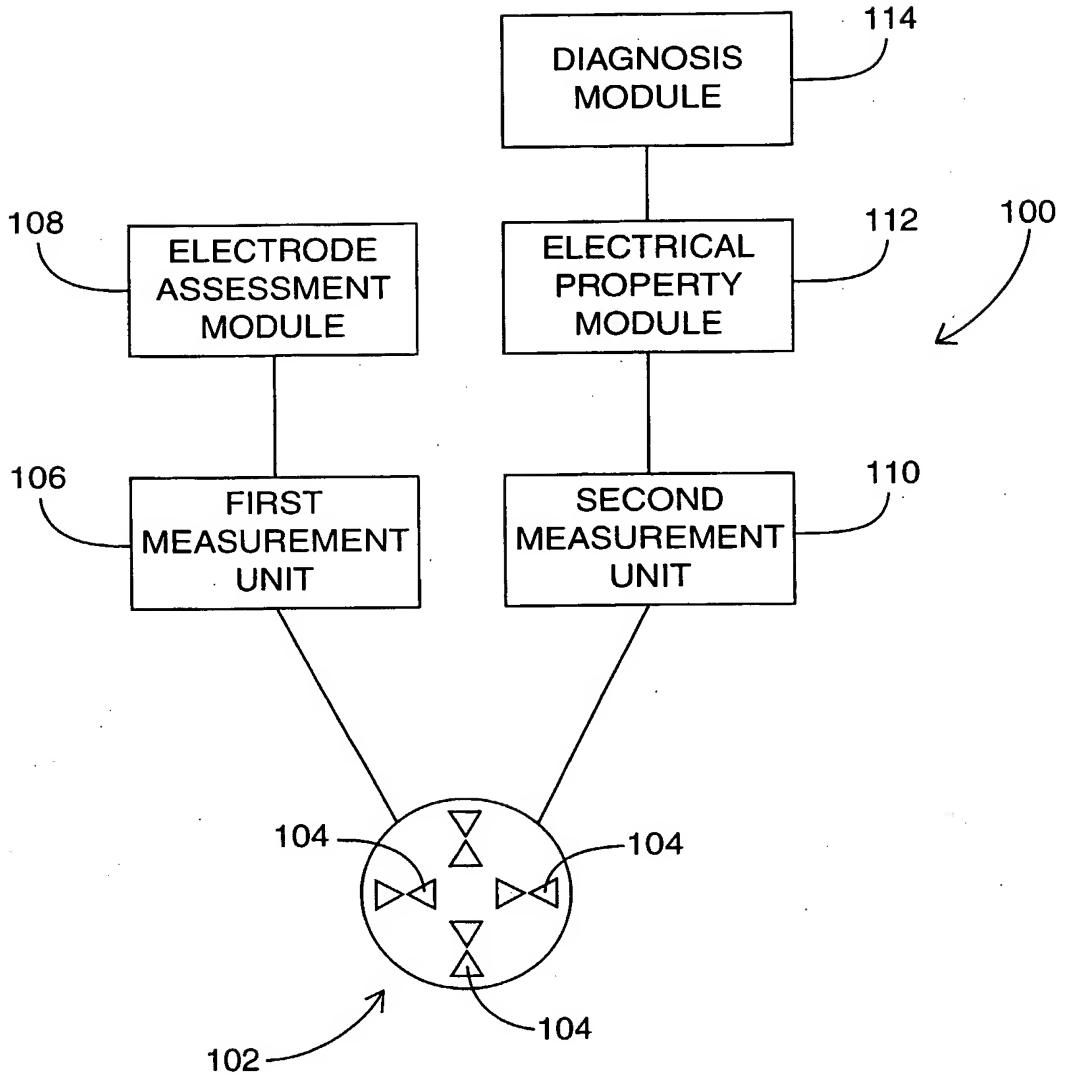
DIAGNOSIS MODULE
114
108
ELECTRODE ASSESSMENT MODULE
ELECTRICAL PROPERTY MODULE
112
100
106
FIRST MEASUREMENT UNIT
SECOND MEASUREMENT UNIT
110
104
104
104
102

FIG. 1

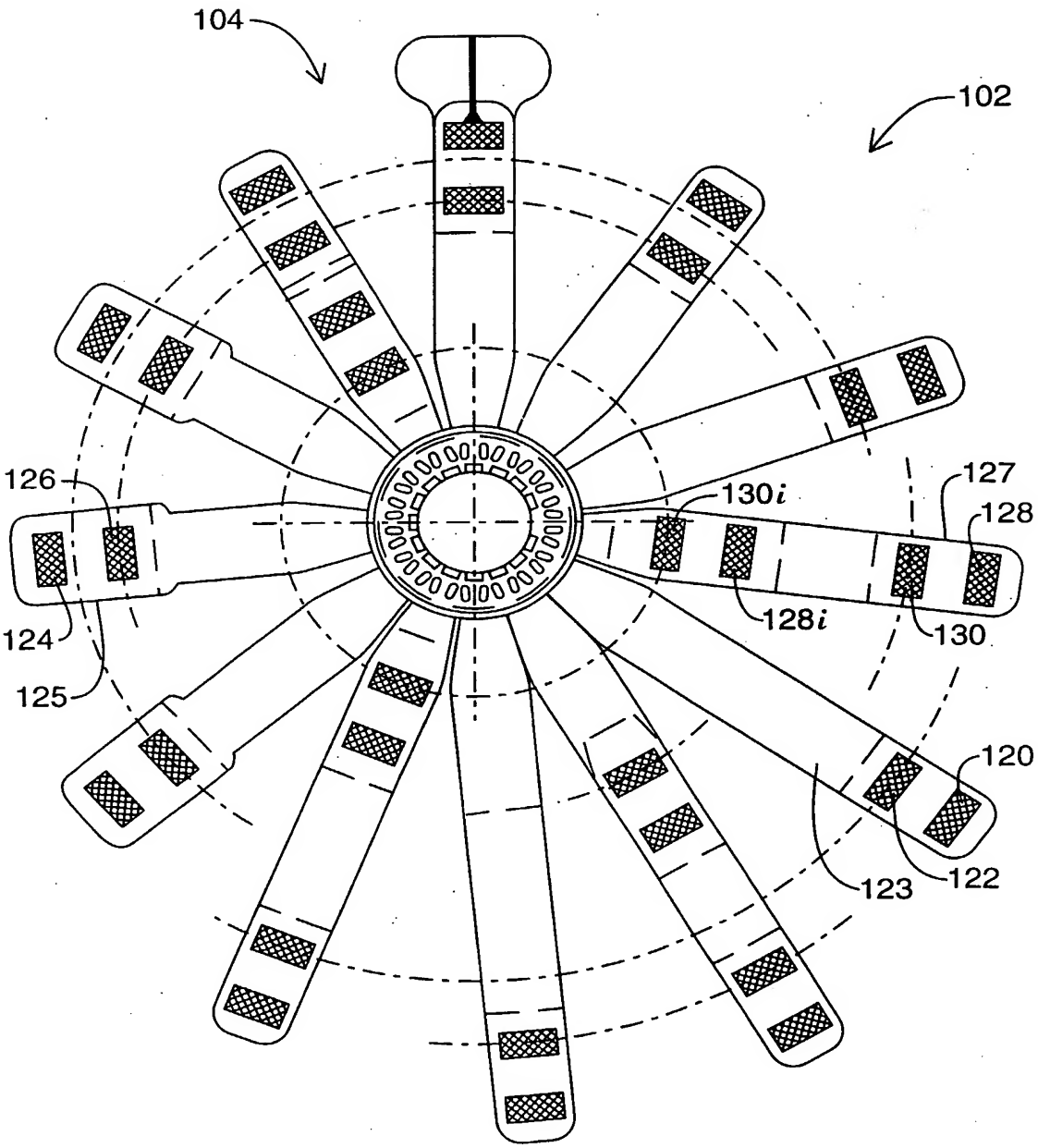

FIG. 2A

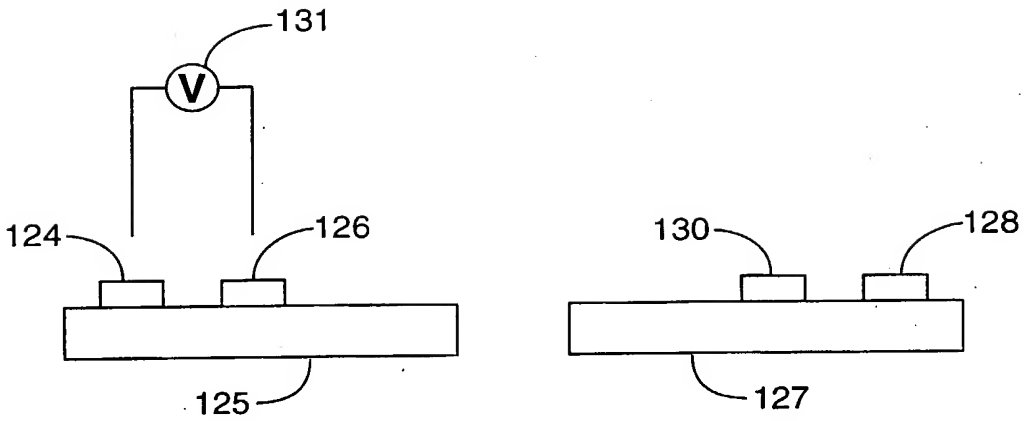

FIG. 2B

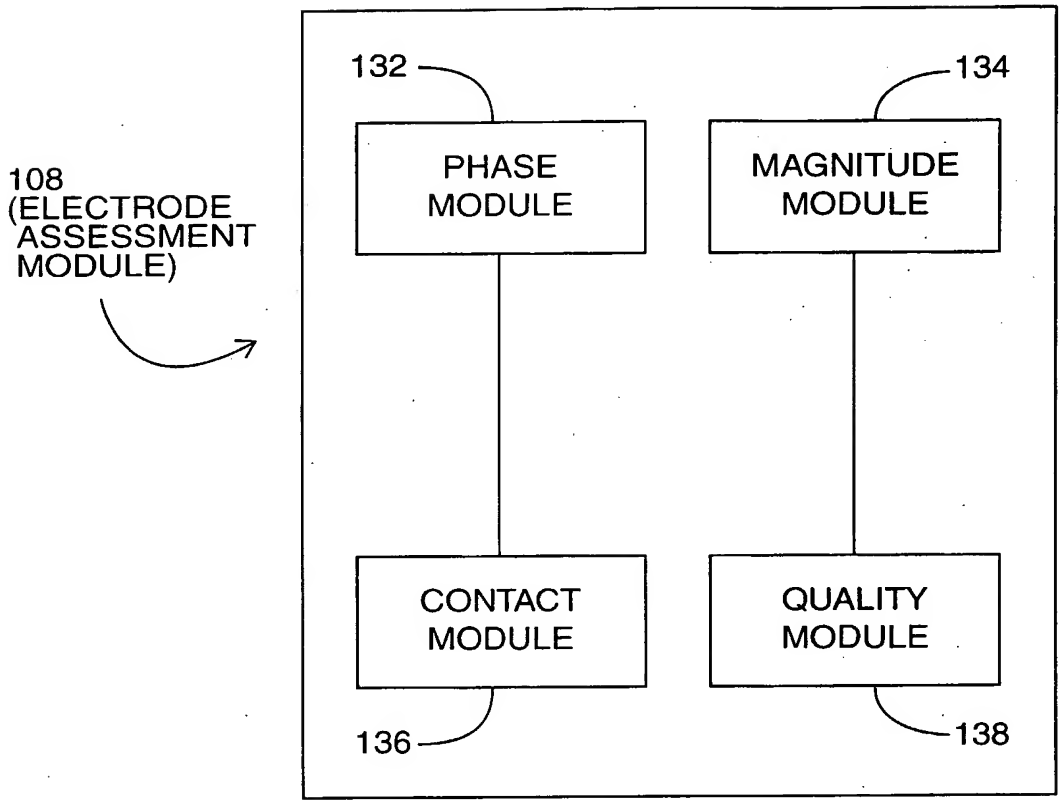
108
(ELECTRODE
ASSESSMENT
MODULE)
132
PHASE
MODULE
134
MAGNITUDE
MODULE
CONTACT
MODULE
136
QUALITY
MODULE
138

FIG. 3

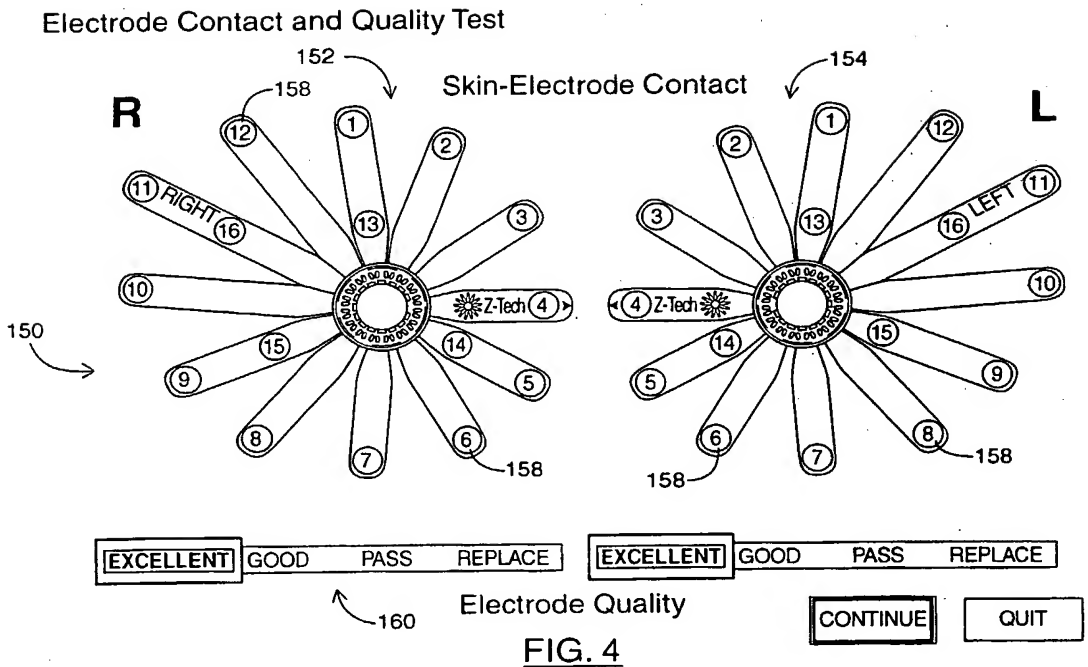
Electrode Contact and Quality Test
152
Skin-Electrode Contact
154
158
R
L
RIGHT
LEFT
Z-Tech
150
158
158
EXCELLENT
GOOD
PASS
REPLACE
EXCELLENT
GOOD
PASS
REPLACE
160
Electrode Quality
CONTINUE
QUIT

FIG. 4

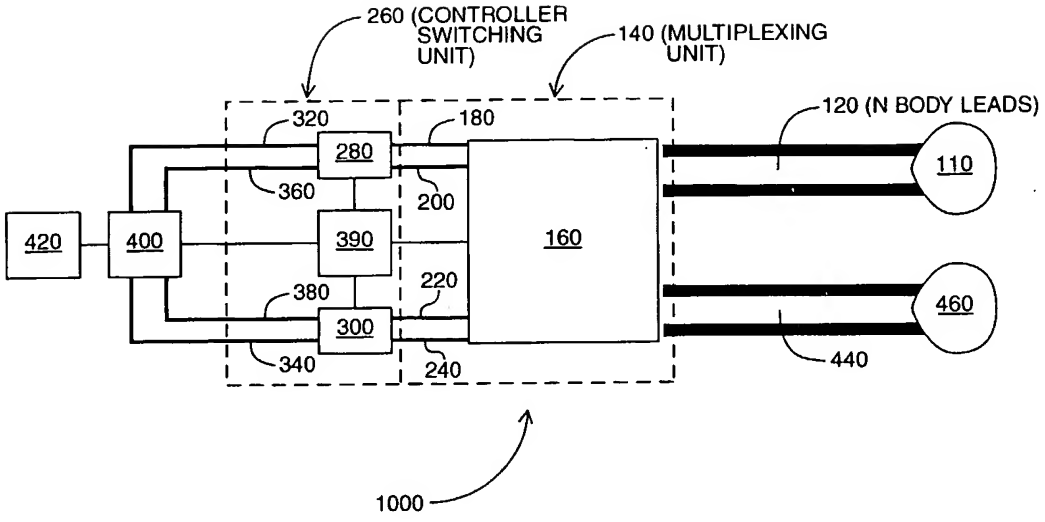
260 (CONTROLLER SWITCHING UNIT)
140 (MULTIPLEXING UNIT)
120 (N BODY LEADS)
320
180
280
110
360
200
420
400
390
160
220
380
460
300
340
240
440
1000

FIG. 5

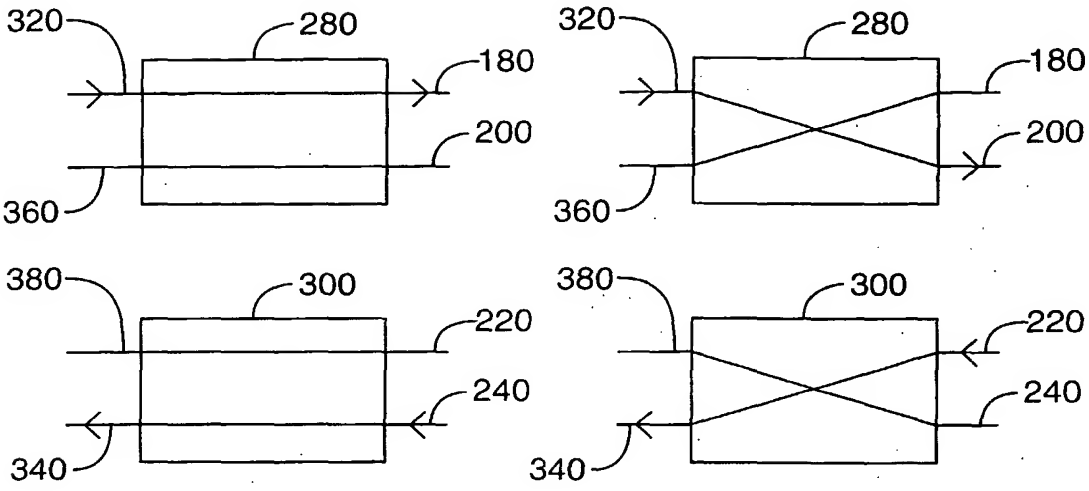

FIG. 6A

FIG. 6B

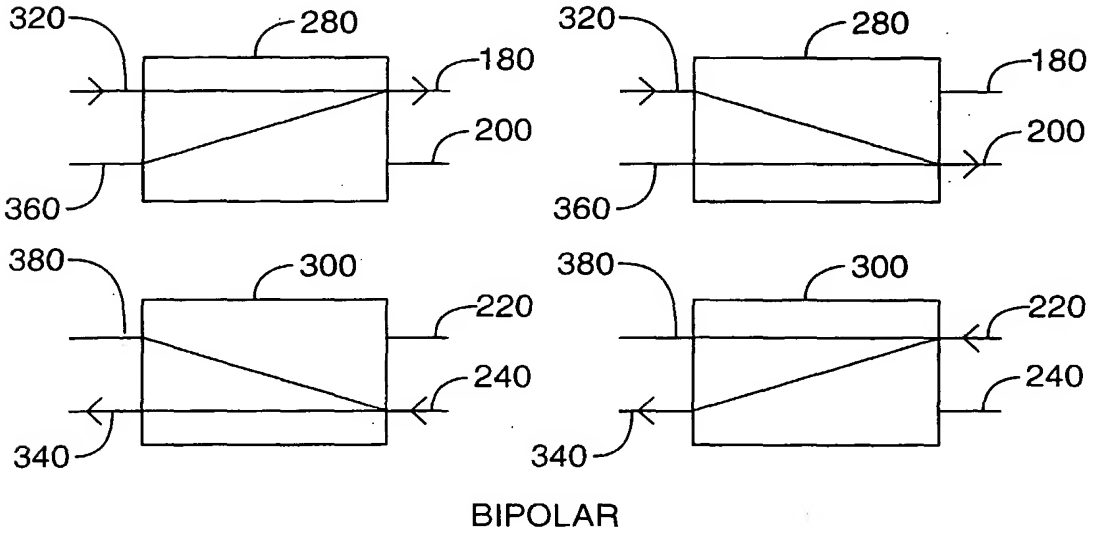

FIG. 6C

FIG. 6D

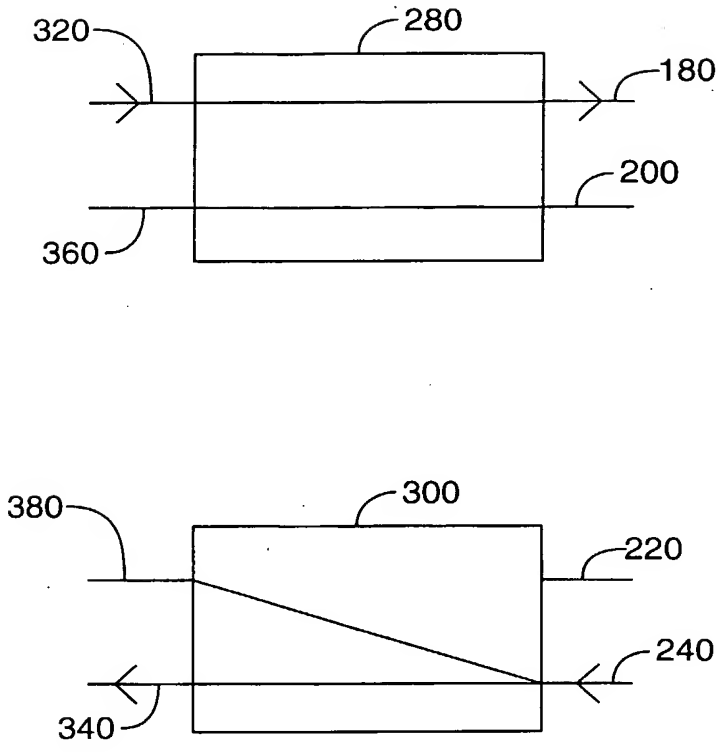

FIG. 7

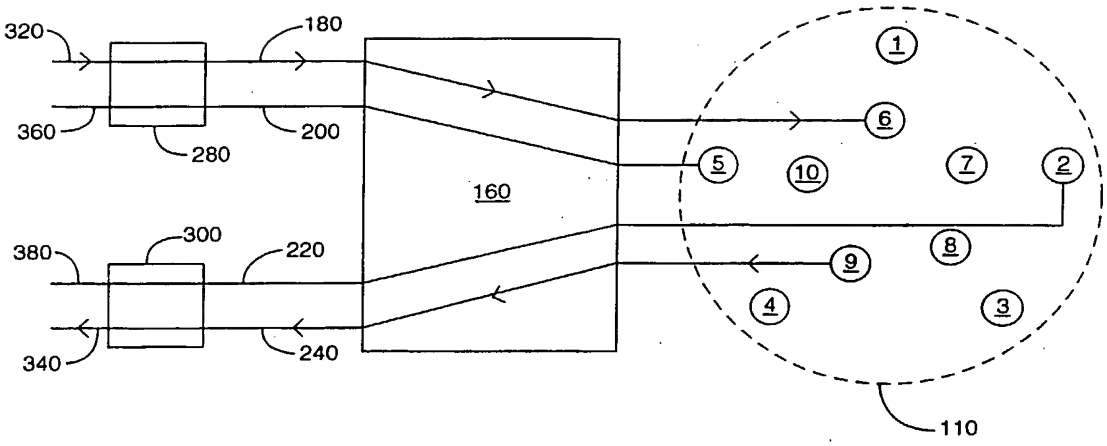

FIG. 8

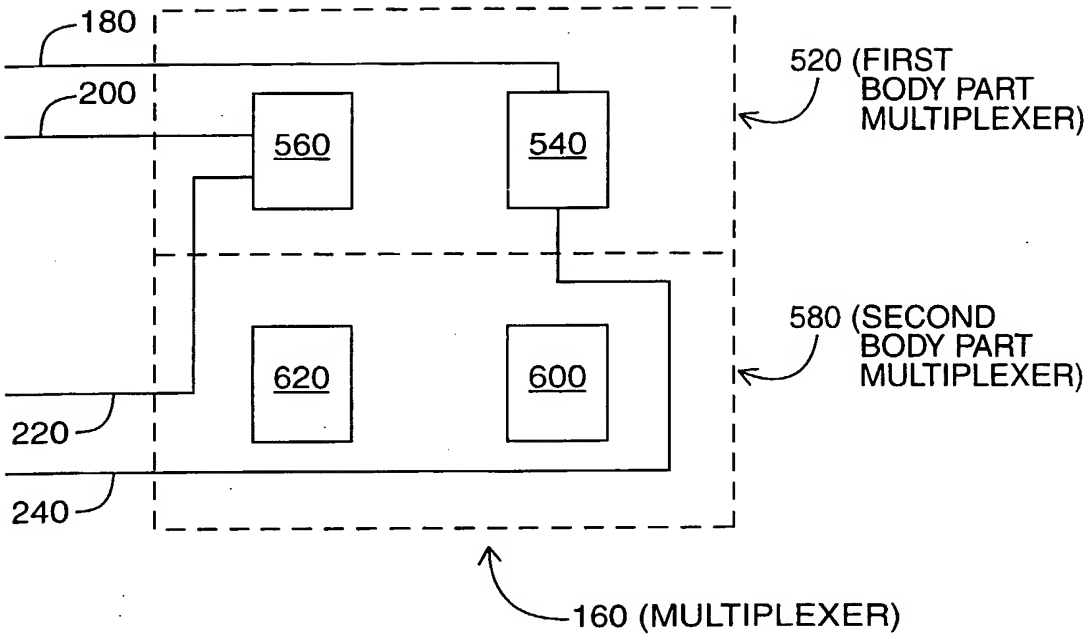
180
200
560
540
520 (FIRST BODY PART MULTIPLEXER)
580 (SECOND BODY PART MULTIPLEXER)
620
600
220
240
160 (MULTIPLEXER)

FIG. 9A

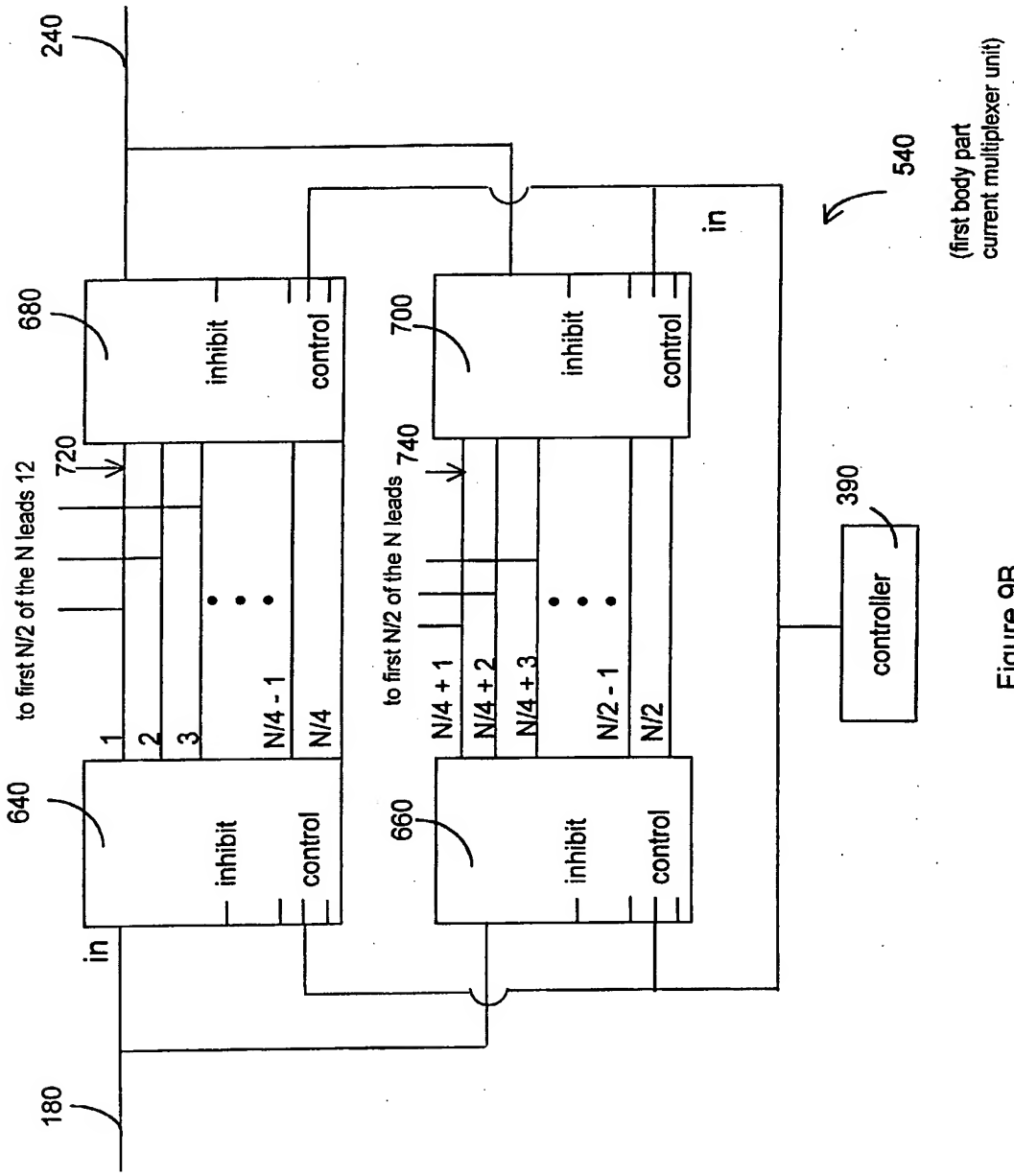
240
680
inhibit
control
700
inhibit
control
720
740
to first N/2 of the N leads 12
to first N/2 of the N leads
1
2
3
N/4 - 1
N/4
N/4 + 1
N/4 + 2
N/4 + 3
N/2 - 1
N/2
640
inhibit
control
660
inhibit
control
in
in
180
540
(first body part current multiplexer unit)
390
controller

Figure 9B

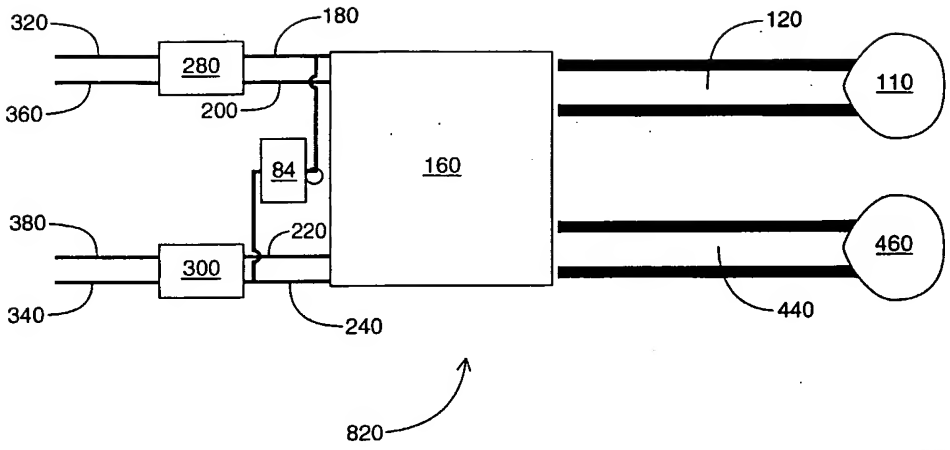
320
180
120
280
110
360
200
84
160
380
220
460
300
340
240
440
820

FIG. 10

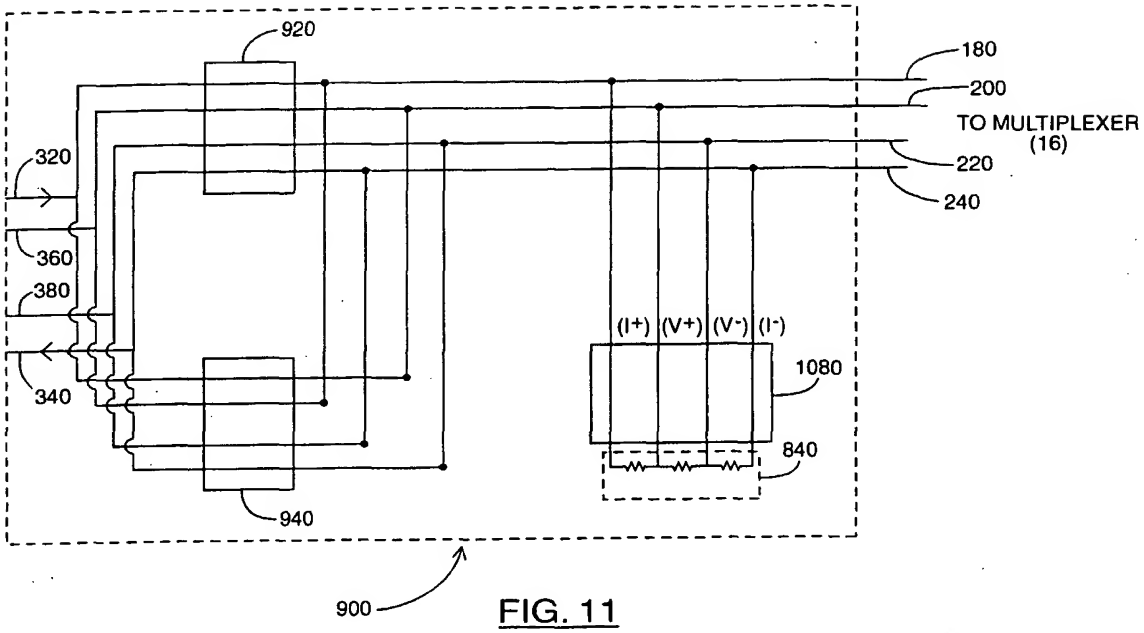
920
180
200
TO MULTIPLEXER
(16)
320
220
240
360
380
340
(I+)
(V+)
(V-)
(I-)
1080
840
940
900

FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 03/01827

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/05 A61B5/04 A61B5/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 415 164 A (FAUPEL MARK L ET AL) 16 May 1995 (1995-05-16) column 3, line 41 -column 4, line 19; claim 1; figure 1	13
A	US 2002/099415 A1 (SCHWARTZMAN DAVID S ET AL) 25 July 2002 (2002-07-25) abstract; claim 1	13,14
A	US 5 146 926 A (COHEN RICHARD J) 15 September 1992 (1992-09-15) column 5, line 54 -column 8, line 69; claim 1	13
A	US 5 879 308 A (RAESAENEN TAISTO) 9 March 1999 (1999-03-09) abstract; claim 1	13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 April 2004	15/04/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Chopinaud, M

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 03/01827

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 099 844 A (FAUPEL MARK L) 31 March 1992 (1992-03-31) column 2, line 41 -column 3, line 34; claim 1 -----	13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 03/01827

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-12
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 03/01827

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